

Date: September 23, 2003

To: POTW Pretreatment Coordinators and Managers

From: Tri-TAC

Subject: SEWER DISPOSAL OF PHARMACEUTICAL WASTE

On behalf of Tri-TAC, we want to provide you with an update on recent guidance developed by the California Department of Health Services regarding the disposal of pharmaceutical wastes into sewer systems, and recommendations for your agency on how to handle this challenging disposal issue. Tri-TAC is a statewide technical advisory group sponsored by the California Association of Sanitation Agencies (CASA), the California Water Environment Association (CWEA), and the League of California Cities. Together these groups represent publicly owned treatment works (POTWs) that collect, treat and reclaim more than two billion gallons of wastewater each day and serve most of the sewered population of California. We believe that the information in this memo will be of assistance in the management of your pretreatment programs in light of new developments that have occurred with regard to the disposal of pharmaceutical wastes. As used in this memo, the term "pharmaceutical" refers to both prescription medications and over-the-counter medications.

By way of background, in October 2002 the California Department of Health Services (DHS) independently issued a memo to hospitals regarding disposal of pharmaceutical wastes, specifically indicating that if a pharmaceutical did not meet the criteria to be either a California or Resource Conservation and Recovery Act (RCRA) hazardous waste (i.e., it was considered "non-hazardous"), then under state law it could be sewered or disposed of with regular trash. This was of great concern to Tri-TAC since we believed many hospitals might have inappropriately believed that all non-hazardous waste pharmaceuticals could be sewered without first seeking permission from the local POTW. In response, Tri-TAC worked with DHS and hospital trade associations to prepare a follow-up memo that clarified which pharmaceutical wastes can be disposed to sewer systems pending POTW authorization. The DHS memo was released on September 5, 2003 and is provided as Attachment 1. The memo has been distributed by DHS to medical facilities. Consequently, medical facilities in your area may be contacting you with questions regarding sewer disposal of pharmaceuticals.

While there is increasing public concern about the presence of pharmaceuticals in surface waters resulting from wastewater discharges, there is also increasing pressure on medical facilities to minimize their disposal costs by sewerage waste pharmaceuticals. Pharmaceuticals that are not sewered must be sent out-of-state by medical facilities for incineration. To help with your decision-making about accepting pharmaceutical wastes into your system, we offer the following recommendations and background information.

Recommendations for Accepting Pharmaceutical Wastes

When Congress adopted the Clean Water Act, it required POTWs to achieve technology-based treatment requirements (secondary treatment), a level of treatment that was intended to remove conventional pollutants from wastewater such as suspended solids and biodegradable organic material - not toxic pollutants. Instead, the control of toxics from indirect dischargers was to be accomplished via local pretreatment requirements (See CWA Section 307(b)(1)) and federal effluent guidelines (See CWA Section 307(a)(2)). Congress clearly recognized that removal of toxic pollutants through treatment by POTWs was the exception, not the rule, and that sewer users must comply with local and federal pretreatment requirements as necessary to maintain the integrity of the POTW wastewater treatment systems. Pharmaceutical wastes do not fall into the general category of conventional pollutants. As such, they should only be accepted by your POTW if they are compatible with the operation of your wastewater treatment plant(s), your wastewater discharge permit(s), and the needs of your water reuse customers, if any.

When you receive a request to discharge a pharmaceutical waste, you should always evaluate the request to ensure that the discharge will not cause interference or pass through¹ and that it complies with all applicable waste discharge laws, including hazardous waste disposal laws, pretreatment standards, and your local ordinance requirements. You should also evaluate the request to ensure that the discharge does not disrupt the operation of the treatment plant, including its biological treatment processes. You may require a discharger to prove that a discharge will not adversely affect human health or aquatic life prior to accepting a waste

In general, medical facilities must obtain specific written permission from you before any wastes, including pharmaceutical wastes, are sewerred.

Although each POTW has the right to deny a request to sewer a waste based on local conditions, the following wastes are **generally acceptable for sewerred**:

- Solutions in IV bags containing *only* saline solution, lactate, nutrients such as glucose (e.g., D5W), vitamins, and added salts such as potassium and/or other electrolytes.

The following wastes are **not acceptable for sewerred**:

¹ Interference means a discharge which inhibits or disrupts the POTW, its treatment processes or operations, or its sludge processes, use or disposal and causes a violation of the POTW's NPDES permit (See 40 Code of Federal Regulations (CFR) Part 403.3(i)); Pass Through means a discharge which exits the POTW into waters of the United States in quantities or concentrations which causes a violation of the POTW's NPDES permit (See 40 CFR Part 403.3 (n)).

- Any hazardous wastes, including both California-only hazardous wastes and federal hazardous wastes regulated under RCRA (Note: additional information that defines these wastes is included in the background section of the memo).

The following wastes **may not be acceptable** for sewerage if they contain materials known or suspected of being toxic to humans, animals, aquatic life, the environment, or to biological or other wastewater treatment processes. This will be of particular importance for POTWs engaged in water recycling or discharge to surface waters:

- Liquid and solid pharmaceutical wastes, such as IV bags containing biologically active materials (e.g., antibiotics, painkillers, and chemotherapy agents) and controlled substances.

Many hospitals currently dispose of excess material in syringes to drains, where they pass into sewer systems. It is highly recommended that medical facilities adopt a best management practice of wasting excess material in syringes into a medical waste container prior to or after the administration of injections. In general, medical facilities should be encouraged to reduce discharges of pharmaceuticals to the sewer to the extent feasible.

You may also receive inquiries from households about disposal of waste pharmaceuticals. **Households should be advised never to flush waste pharmaceuticals down the toilet.** In most cases, waste pharmaceuticals, including over-the-counter medications, should be taken to household hazardous waste collection events. Controlled substances, such as narcotics and tranquilizers, should be mixed with undesirable trash to render them unrecoverable and put out with ordinary household trash.

Background Information

1. Why are pharmaceuticals in water and wastewater of concern to POTWs?

Recent studies have identified pharmaceuticals and chemicals in personal care products in lakes and streams nationwide, and many of these pollutants are believed to be coming from municipal wastewater discharges. There is increasing concern that the pharmaceuticals present in surface waters could cause various disruptive environmental effects, including endocrine disruption in aquatic life and increased antibiotic resistance. The impacts of pharmaceuticals in surface waters, including effects on aquatic life development and effects on human development, are still being studied. While these studies are occurring, it is reasonable and prudent to be cautious about accepting pharmaceutical wastes into your sewer system.

The most extensive study of pharmaceuticals in surface waters thus far was performed by the United States Geological Survey during 1999 and 2000. (A copy of the study can be obtained at http://pubs.acs.org/hotartcl/est/es011055j_rev.html; subsequent to the publication of the study in the Journal of Environmental Science

and Technology, USGS published at errata which can be found at http://toxics.usgs.gov/regional/est_errata.html) The study found that pharmaceuticals were commonly present in the surface waters studied including over-the-counter drugs such as acetaminophen and ibuprofen. Antibiotics were also identified, including erythromycin, lincomycin, sulfamethoxazole, and trimethoprim. Steroids and hormones were also commonly found, including 17 β -ethynyl estradiol, a hormone used in birth control pills. Other prescription drugs were identified such as codeine and the antihypertensive drug, diltiazem.

For many of these substances, experts have incomplete understandings of their toxicological significance to humans and aquatic life. While they may not cause acute toxicity in aquatic organisms, they may interfere with endocrine systems, particularly when exposure occurs during developmentally sensitive times such as before birth. There is also concern that the occurrence of antibiotics in water is associated with the incidence of antibiotic-resistant bacteria.

2. How do medical waste regulations apply to pharmaceuticals in California?

Disposal of medical wastes in California is regulated by the Medical Waste Management Act (MWMA), codified in the Health and Safety Code (HSC), Sections 117600 to 118360. This program is administered by DHS.

Under the MWMA, there are several types of waste pharmaceuticals:

- a) RCRA-hazardous waste pharmaceuticals. If a waste pharmaceutical is defined as a RCRA-hazardous waste, it must be managed as a hazardous waste and cannot be sewered. A waste pharmaceutical falls into this category if it is a listed waste or has the characteristics of a hazardous waste. The full regulations governing RCRA-hazardous waste characterization can be found in 40 CFR Part 261. Guidance on classification of RCRA wastes can be found at www.epa.gov/epaoswer/general/orientat . A good reference article on RCRA regulations as they apply to pharmaceuticals is "Managing Pharmaceutical Waste: What Pharmacists Should Know," Charlotte Smith, *Journal of the Pharmacy Society of Wisconsin*, Nov/Dec 2002. A copy may be found on-line at [www.pharmacology.com/pedd/pdf/Managing Pharmaceutical Waste.pdf](http://www.pharmacology.com/pedd/pdf/Managing%20Pharmaceutical%20Waste.pdf).
- b) Radioactive wastes. These are regulated under the Radiation Control Law. See the HSC starting with Section 114960.
- c) Medical wastes. Section 117635(g) of the HSC defines all pharmaceutical wastes that are not RCRA or radioactive wastes to be biohazardous wastes. Per HSC Section 118222, biohazardous wastes that are pharmaceuticals must be incinerated. Therefore, as written, according to California law, waste pharmaceuticals that are not RCRA-hazardous nor radioactive must be

incinerated thereby implying that waste pharmaceuticals may not be disposed of with ordinary trash or sewerage.

However, a controversy has arisen over interpretation of the MWMA as it relates to pharmaceuticals. Although the MWMA states that all pharmaceuticals are biohazardous wastes, the author (Cathie Wright) of this provision of the law (from Senate Bill 1966, enacted in 1996) wrote a letter stating that this is not the intent of the law. She contends that the intent of the law was only to regulate as biohazardous waste those pharmaceuticals that would otherwise be characterized as California-only hazardous wastes. DHS has chosen to rely on Senator Wright's interpretation of the law, and thus does not regulate pharmaceuticals as biohazardous wastes if they are not radioactive, not RCRA-regulated, and would not be characterized as California-only hazardous waste.

Tri-TAC has discussed this issue extensively with DHS, but DHS is unwilling to change its current interpretation. As a compromise, Tri-TAC worked with DHS on the September 5, 2003 guidance memo for medical facilities that explains local POTW authority over materials that may be sewerage, and informs medical facilities that they must have authorization from their POTW to discharge waste pharmaceuticals. **It is up to individual POTWs to determine which non-radioactive, non-hazardous waste pharmaceuticals they are willing to accept.**

If you have questions about medical waste management, contact the DHS Medical Waste Management Program at 906/327-6904 or MedWasteInfo@dhs.ca.gov.

3. What regulations apply to household pharmaceutical waste?

State law exempts medical and biohazardous waste generated by households from regulation under medical waste laws, per HSC Section 117670. This includes pharmaceutical waste. Therefore, waste pharmaceuticals generated by households are not classified as medical wastes and most may be handled by household waste collection programs. The exception is waste pharmaceuticals that are classified as controlled substances, such as narcotics and tranquilizers. These are regulated by the Federal Drug Enforcement Agency and thus may not be handled by household hazardous waste programs without special permitting.

4. Where can I get information on pollution prevention for medical facilities?

Hospitals for a Healthy Environment (H2E) is a joint project of the American Hospital Association, the Environmental Protection Agency, Health Care Without Harm, and the American Nurses Association. The primary goal of the H2E effort is to educate health care professionals about pollution prevention opportunities in hospitals and health care systems. General information about pollution prevention for hospitals can be found on the H2E web site at www.h2e-online.org.

5. How does the Clean Water Act relate to control of pharmaceutical wastes?

Section 307 of the Federal Water Pollution Control Act (more commonly referred to as the Clean Water Act) called for the Environmental Protection Agency to develop national pretreatment standards to control industrial discharges into sewerage systems. Included in this program are "Prohibited Discharge Standards," which are uniform national requirements that restrict the level of pollutants that may be discharged by nondomestic sources to sanitary sewer systems. All POTWs that are required to implement a Pretreatment Program must enforce the federal standards. Prohibited Discharge Standards specifically prohibit the discharge of pollutants that cause pass through or interfere with a POTW's operations.² Wastewater discharge permits issued by the California Regional Water Quality Control Boards for POTWs generally contain a requirement that wastes discharged shall not contain any substances in concentrations toxic to human, animal, plant, or aquatic life. This means that no pharmaceutical wastes may be sewered that in and of themselves, or in conjunction with other wastes discharged by businesses or households, could create a concentration of the pharmaceutical in the treatment plant effluent that, when discharged to surface or groundwater, adversely impacts humans or aquatic life. Individual POTWs have the authority to determine what wastes may adversely impact their systems.

6. How do California's hazardous waste regulations apply to pharmaceutical waste discharges?

The California Environmental Protection Agency's Department of Toxic Substances Control (DTSC) implements hazardous waste regulations in California, along with various local agencies. California does not allow hazardous wastes to be sewered (See California Code of Regulations, Sections 66261.3 and 66261.4). Hazardous wastes may be listed wastes or characteristic wastes. Listed hazardous wastes include epinephrine, nitroglycerin, and many chemotherapy agents. Characteristics that make a waste a hazardous waste include ignitability (including formulations with more than 24% alcohol and oxidizers such as potassium permanganate and silver nitrate); corrosivity (having a pH less than 2 or greater than 12.5); reactivity (including nitroglycerin, which is generally exempt from federal hazardous waste regulations but not California hazardous waste regulations); and toxicity.

Although the hazardous characteristics mentioned above are chemical properties easily ascertained, a number of factors must be considered in determining if a waste exhibits the characteristic of toxicity under California standards. A group of specified chemical must not be present in concentrations in excess of that listed in the California Code of Regulations Sections 66261.24(a)(1) and 66261.24(a)(2). The material must also not have an acute oral LD₅₀ less than 2,500 mg/kg, an acute dermal LD₅₀ less than 4,300 mg/kg, an acute inhalation LC₅₀ less than 10,000 parts per million as a gas or vapor, or an acute aquatic 96-hour LC₅₀ less than 500 mg/L when

² Ibid.

measured in soft water using fathead minnows, rainbow trout, or golden shiners. Additionally, a waste is hazardous waste if "it has been shown through experience or testing to pose a hazard to human health or environment because of its carcinogenicity, acute toxicity, chronic toxicity, bioaccumulative properties or persistence in the environment."

The generator of a waste has the responsibility to determine whether a waste is a hazardous waste or not. For pharmaceutical wastes, all criteria that may reasonably be expected to make a waste a hazardous waste need to be explored before a waste can be disposed of as non-hazardous. Improper determination of whether a waste is hazardous does not shield the generator from felony criminal liability for illegal hazardous waste disposal.

7. What is the California Integrated Waste Management Board's (CIWMB's) policy on disposal of pharmaceutical wastes?

In cooperation with U.S. EPA Region 9, DHS, and DTSC, the CIWMB has developed a page on its website dedicated to disposal of medical waste. CIWMB specifically advises homeowners to "not put pharmaceuticals down the drain or down the toilet." There is also information on why it is important not to dispose of pharmaceuticals and personal care products via sewers. The CIWMB also advises that if pharmacy take-back programs are not available or if local household hazardous waste facilities do not accept pharmaceuticals, then disposing of pharmaceuticals in the trash is the best option. "If you dispose pharmaceuticals in the trash, please secure them in some sort of durable packaging to ensure that they make it to the landfill." (See <http://www.ciwmb.ca.gov/WPIE/HealthCare/PPCP.htm>)

Further Information

If you have any questions about the information in this memo, please contact Ann Heil of the Sanitation Districts of Los Angeles County by phone at 562/699-7411, extension 2950, or by e-mail at aheil@lacsdc.org.

For general information about Tri-TAC, visit www.tritac.org or contact Emily Estrada at eeestrada@lacsdc.org.

The California Health and Safety Code may be found at www.leginfo.ca.gov/calaw.html.


The Code of Federal Regulations may be found at <http://www.access.gpo.gov/nara/cfr/index.html>.

For more information on hazardous waste regulations and disposal, please contact DTSC (See www.dtsc.ca.gov) or your local hazardous waste agency (known as a Certified Unified Program Agency or CUPA). (See www.calcupa.net for a list of CUPAs in California.)

Memorandum

Date: September 5, 2003

To: Directors of Environmental Health
Medical Waste Program Managers
California Healthcare Association

From: Jack McGurk, Chief 
Environmental Management Branch

Subject: SEWER DISPOSAL OF PHARMACEUTICAL WASTE

The purpose of this memo is to clarify issues regarding the disposal of pharmaceutical wastes into wastewater sewerage systems. While the Department of Health Services' (DHS) October 15, 2002, pharmaceutical waste memo covered characterization information regarding State law, it did not address local laws, especially those of California wastewater agencies (also known as publicly owned treatment works or POTWs). This memo builds upon the earlier memo to include information regarding pharmaceutical disposal as it relates to POTWs.

The discharge of waste to sewerage systems is highly regulated throughout California by the federal Clean Water Act and by the state's Porter-Cologne Water Quality Act as codified in the Water Code. California law also prohibits the discharge of hazardous wastes to wastewater sewerage systems. POTWs have additional local authority specified in ordinances to restrict the discharge of materials to their systems. Wastes from medical facilities may not be discharged to sewers without the prior authorization of the POTW operating the sewers.

Guidance

In order to obtain authorization to discharge waste pharmaceuticals to a sewerage system, ***it is first necessary to contact the POTW that provides sewerage services in your area.*** Wastewater treatment plants are designed to remove conventional pollutants such as suspended solids and easily biodegradable organic material, not other pollutants such as pharmaceuticals. Other pollutants are only accepted by POTWs if they are compatible with the POTW's operations and discharge requirements.

The POTW will evaluate your request to ensure that the discharge is in conformance with all applicable laws and regulations and will not cause a violation of any pertinent waste discharge and/or water reclamation requirement. The POTW will also evaluate your request to ensure that the discharge does not interfere with the operation of the treatment plant, including its biological treatment processes. The POTW may require a discharger to prove that the waste is non-hazardous and/or that the



discharge of the waste to the sewerage system will not adversely affect humans or aquatic life prior to accepting a waste.

In general, specific written permission *must* be obtained from your POTW before any wastes, including pharmaceutical wastes, are sewerred.

Although each POTW has the right to deny a request to sewer a waste based on local conditions, the following wastes are generally **acceptable for sewerred**:

- Solutions in IV bags containing *only* saline solution, lactate, nutrients such as glucose (e.g., D5W), vitamins, and added salts such as potassium and/or other electrolytes.

The following Wastes are **not acceptable for sewerred**:

- Any hazardous wastes, both California-only hazardous wastes and federal hazardous wastes regulated under RCRA.

The following wastes may not be acceptable for sewerred if they contain materials known or suspected of being toxic to humans, animals, aquatic life, the environment, or to biological or other wastewater treatment processes. This will be of particular importance for POTWs engaged in water recycling or discharge to surface waters:

- Liquid and solid pharmaceutical wastes, such as IV bags containing biologically active materials (e.g., antibiotics, painkillers, and antineoplastics) and controlled substances.

In general, medical facilities are encouraged to reduce discharges of pharmaceuticals to the sewer to the extent feasible. If you have any questions about the discharge of a specific waste into the sewerage system, please contact your local POTW. To obtain contact information for your POTW, check your utility or property tax bills to see who provides your sewer service or call your city and ask who provides sewer services in your area.

Background Information.

1. *Why are pharmaceuticals in water and wastewater of concern to POTWs?*

There is increasing concern that the pharmaceuticals present in surface waters could cause various disruptive environmental effects, including endocrine disruption in aquatic life and increased antibiotic resistance. Studies have identified pharmaceuticals and chemicals in personal care products in lakes and streams nationwide, and many of these pollutants are believed to be coming from wastewater discharges. The impact of pharmaceuticals in surface waters, including effects on aquatic life development and effects on human development, is still being studied. While these studies are occurring it is reasonable and prudent to be cautious about sewerage waste pharmaceuticals.

2. *What is the Clean Water Act and how does it relate to the control of pharmaceutical wastes?*

Section 307 of the Federal Water Pollution Control Act (more commonly referred to as the Clean Water Act) called for the Environmental Protection Agency to develop national pretreatment standards to control industrial discharges into sewerage systems. Included in this program are "Prohibited Discharge Standards," which are uniform national requirements that restrict the level of pollutants that may be discharged by non-domestic sources to sanitary sewer systems. All POTWs that are required to implement a Pretreatment Program must enforce the federal standards. Prohibited Discharge Standards specifically prohibit the discharge of pollutants that cause "pass-through" or interfere with a POTW's operations. A pass-through is a discharge that, alone or in conjunction with discharges from other sources, results in non-compliance with any requirement of a POTW's discharge permit, per 40 Code of Federal Regulations, Part 403.5(a)(1). Wastewater discharge permits issued by the California Regional Water Quality Control Board for POTWs pursuant to the Clean Water Act generally contain a requirement that wastes discharged shall not contain any substances in concentrations toxic to human, animal, plant, or aquatic life. This means that no pharmaceutical wastes may be sewerage that in and of themselves, or in conjunction with other wastes discharged by businesses or households, could create a concentration of the pharmaceutical in the treatment plant effluent that, when discharged to surface or groundwater, adversely impacts humans or aquatic life. Individual POTWs have the authority to determine what wastes may adversely impact their own systems.

3. *How do California's hazardous waste regulations apply to pharmaceutical waste discharges?*

The California Environmental Protection Agency's Department of Toxic Substances Control (DTSC) implements hazardous waste regulations in California, along with various local agencies. California does not allow hazardous wastes to be sewerage (California Code of Regulations, Sections 66261.3 and 66261.4). Hazardous wastes may be listed wastes or characteristic wastes. Listed hazardous wastes include epinephrine, nitroglycerin, and many chemotherapy agents. Characteristics that make a waste a hazardous waste include ignitability (including formulations with more than 24% alcohol,

collodion, and oxidizers such as potassium permanganate and silver nitrate), corrosivity (having a pH less than 2 or greater than 12.5), reactivity (including nitroglycerin, which is generally exempt from federal hazardous waste regulations, but not California hazardous waste regulations), and toxicity.

Although the hazardous characteristics mentioned above are chemical properties easily ascertained, a number of factors must be considered in determining if a waste exhibits the characteristic of toxicity under California standards. A group of specified chemicals must not be present in concentrations in excess of that listed in the California Code of Regulations Sections 66261.24(a)(1) and 66261.24(a)(2). The material must also not have an acute oral LD₅₀ less than 2,500 mg/kg, an acute dermal LD₅₀ less than 4,300 mg/kg, an acute inhalation LC₅₀ less than 10,000 parts per million as a gas or vapor, or an acute aquatic 96-hour LC₅₀ less than 500 mg/L when measured in soft water using fathead minnows, rainbow trout, or golden shiners. Additionally, a waste is hazardous waste if “it has been shown through experience or testing to pose a hazard to human health or environment because of its carcinogenicity, acute toxicity, chronic toxicity, bioaccumulative properties or persistence in the environment.” Violation of any of these criteria makes the waste a hazardous waste.

The generator of a waste has the responsibility to determine whether a waste is hazardous or not. For pharmaceutical wastes, all criteria that may reasonably be expected to make a waste a hazardous waste need to be explored before contacting a POTW to seek authorization to discharge the waste. Improper determination of whether a waste is hazardous does not shield the generator from felony criminal liability for illegal hazardous waste disposal. For more information on hazardous waste regulations and disposal, please contact DTSC (www.dtsc.ca.gov) or your local hazardous waste authority (known as a Certified Unified Program Agency or CUPA. See www.calcupa.net for a list of CUPAs in California.)